



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

June 25, 2002

Danielle LaRochelle
Registration Product Manager
Aventis CropScience USA
P.O. Box 12014
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Re: Second Error Correction of Carbaryl Risk Assessments

Dear Ms. LaRochelle:

Within two weeks from the date of this letter, please identify and comment on any errors in the enclosed risk assessment documents for carbaryl, addressing only typographic, mathematical, or computational-type errors. The enclosed documents include the human health and the environmental fate and effects risk assessments. Also enclosed for your reference are supporting documents for the human health risk assessment. Last August, Aventis completed its first error correction review of these documents. As a courtesy, EPA is offering Aventis a second error correction review of these documents because of substantive changes described later in this letter.

On receiving your error correction submission, the Agency will evaluate your comments and will revise the risk assessments as necessary. At this phase, EPA will not address comments concerning matters of policy, interpretation, or applicability of data. Aventis will have ample opportunity to submit such comments during the 60-day public comment period that will begin in the next few weeks.

As part of your two week review, please also inform the Agency in writing of any claims of confidential business information (CBI) contained in these documents. If we do not receive notice in writing of any such claims within the two weeks, we will assume the document is free of CBI.

Please send, in writing, the results of your error correction and CBI review to:

Anthony Britten
US EPA (7508C)
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
E-mail Address: britten.anthony@epa.gov
Fax: (703) 308-8005

Background

EPA is offering this second courtesy error review because of substantive changes to the risk assessments. These changes were prompted by new data Aventis submitted since its first error correction review. The new data includes a two-generation rat reproduction study, data from a developmental neurotoxicity study, and three dermal studies. EPA also rereviewed carbaryl under the latest cancer assessment guidelines.

The two weeks offered for this error review coincides with the time necessary to publish the Federal Register notice announcing the start of the Phase 3 public comment period. The publication process is now underway. Two weeks is also the period EPA usually offers for a second review of typographic, mathematical or computational-type errors.

As part of its Phase 1 error review, Aventis submitted substantive comments to the Agency. EPA generally does not consider substantive comments received during Phase 1. However, in this case, EPA considered the comments while awaiting and then analyzing the new data from Aventis. EPA will specifically respond to these comments in a document prepared at the end of phase 3. You need not resubmit your substantive comments.

Please keep your review in the next two weeks focused *solely* on typographic, mathematical or computational-type errors. Again, Aventis will also have the full 60-days of Phase 3 to submit further substantive comments, which EPA will address in its next revision of the risk assessments. The appropriate level of detail for your error response would be the amount of information that would fit in the margins of a pen-and-ink markup. In fact, a pen-and-ink markup would be the preferred response. Please complete your review of the comprehensive risk assessments before focusing attention on the supporting documents. Prioritizing your review in this way will help ensure the most significant corrections are made in a timely way. Sending corrections “piecemeal” is also recommended. Adopting these standards of review should allow both Aventis and EPA enough time to correct the enclosed documents before their release for Phase 3 public comment.

If you have questions about this request, please contact Anthony Britten, the Chemical Review Manager for carbaryl, at (703) 308-8179.

Sincerely,

//signed by Anthony Britten for//

Betty Shackleford, Acting Associate Director
Special Review and Reregistration Division

Enclosures